REMARKS

I. Preliminary Remarks

The amendments to the specification at page 11 correct typographical errors and do not add new matter to the specification.

The amended claims are directed to methods of stimulating hematopoietic stem cell and primordial germ cell growth and survival comprising contacting a stem cell with a polypeptide that is 95% identical to the amino acid sequence of SEQ ID NO: 13, 32 and 34. Polypeptides that are 95% identical to the amino acid sequences taught in the specification are supported at page 20, lines 26-30. Hematopoietic stem cells and primordial germ cells are supported in the specification at page 11, lines 24-26. These amendments do not add new matter.

II. The rejection under 35 U.S.C. § 112, first paragraph for lack of enablement should be withdrawn.

The Examiner maintained the rejection of claims 62-65 and 74-77 under 35 U.S.C. §112, first paragraph, for assertedly failing to comply with the enablement requirement. The Applicants traverse this rejection.

The Examiner states that the specification does not enables ex vivo methods of using polypeptides comprising an amino acid sequence at least 85% identical to the amino acid sequence of SEQ ID NO: 13, 32 or 34 that exhibit stem cell growth factor activity. However, the polypeptides identified and disclosed in the specification are greater than 85% identical to each other. In particular, the polynucleotide sequence of SEQ ID NO: 12 which encodes the amino acid sequence of SEQ ID NO: 13 is described in Examples 1-5 (pages 164-168). The polynucleotide sequence of SEQ ID NO: 33 is 98.5% identical to SEQ ID NO: 12 and encodes an amino acid sequence (SEQ ID NO: 34) that is 100% identical to SEQ ID NO: 13. The murine polynucleotide sequence of SEQ ID NO: 31 is 88.5% identical to SEQ ID NO: 12 and encodes an amino acid sequence (SEQ ID NO: 32) that is 87.1% identical to SEQ ID NO: 13. The identification and cloning of SEQ ID NO: 33 is described in Example 13 (pages 180-181). Thus, the Applicants teach how to make and use variants that are at least 85% identical to the amino acid sequence of SEQ ID NO: 13, 32 or 34.

In order to expedite prosecution, claims 62 and 76 have been amended to recite polypeptides that are 95% identical to the amino acid sequence of SEQ ID NO: 13, 32

or 34. The structural and functional limitations recited in amended claims 62 and 76 along with teaching of various substantially similar sequences enables one of skill in the art to make and use the recited polypeptide variants. The claimed variants must be at least 95% identical to SEQ ID NOS: 13, 32 and 34 and therefore do not have substantial structural variation from the sequences taught in the specification. In addition, the claimed variants are limited to polypeptides that exhibit stem cell growth factor activity. The activities encompassed by the term "stem cell growth factor activity" are set out in the specification at pages 91, line 23 through page 92, line 7. The specification teaches assays to measure the stem cell growth factor activity at page 89, line 29 through page 92, line 20, and provides working examples demonstrating that the disclosed polypeptides increase stem cell growth and survival. In particular, the Examiner notes in paragraph 2 of the Action (page 2) that Examples 6 and 17 of the specification demonstrate that the SCR-1 polypeptide of the present invention promotes stem cell proliferation and survival.

Claims 62 and 76 recite polypeptides that are substantially similar to those amino acid sequences disclosed in the specification, and have the functional limitation that the recited polypeptide variants exhibit stem cell growth factor activity that is described in the specification. Therefore, amended claims 62, 64 and 74-76 are enabled by the specification

The Examiner also rejected claim 65 as it encompasses a method of promoting proliferation of a stem cell or germ cell in vivo. In the foregoing amendment, claim 65 was amended to be directed to ex vivo methods. Thus, the rejection of claim 65 should be withdrawn in this respect.

The Examiner also stated that the specification does not enable one of skill in the art to stimulate proliferation and survival of all possible stem cells and germ cells, and isolation of all type of stem cells and germ cells would require undue experimentation. The Applicants contemplate that the polypeptide of the present invention will stimulate proliferation and survival in many cell types (see page 20, lines 26-30). One of skill in the art would expect a polypeptide with stem cell growth factor activity to stimulate proliferation and survival in many cell types. Studies on the known stem cell factor (also known as kit ligand or steel factor) demonstrate that this cytokine stimulates primordial germ cell survival (Dolci *et al,. Nature* 352: 809-811, 1991), melanocyte survival (Murphy *et al., Dev. Biol.* 152: 396-401, 1992), hematopoietic progenitor cell proliferation, (Migliacco *et al.,* 88:7420-

7424, 1991), erythroid cell colony formation (Papayannopolou *et al., Blood* 81: 299-310, 1993) and mature (Dolci *et al., Nature* 352: 809-811, 1991) and immature mast cell proliferation and survival (Durand *et al., Blood* 84: 3667-3674, 1994). (See references attached as Appendix A). However, to expedite prosecution, the amended claims are directed to methods of stimulating hematopoietic stem cells and primordial germ cells, which the Examiner admits is enabled by the specification (see Action page 6).

In light of the foregoing amendment and remarks, the Applicants request the rejection of claims 62-65 and 74-75 under 35. U.S.C. § 112, first paragraph for lack of enablement be withdrawn.

CONCLUSION

The Applicants respectfully request entry of the foregoing amendment, as this amendment puts the application in better condition for allowance pursuant to 37 C.F.R. § 1.116. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and to pass this application to issue.

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Respectfully submitted,

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